



ATTORNEY'S DOCKET NUMBER: 2003882-0016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bipin Chandra Muljibhai Patel Examiner: Unassigned
Serial No.: 10/500,495 Art Unit: Unassigned
Filed: June 28, 2004
For: DELIVERY OF NEUTRON CAPTURE ELEMENTS FOR NEUTRON CAPTURE THERAPY

Mail Stop: Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

| Certificate of Mailing | |
|--|------------------|
| I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop: Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. | |
| Date | Signature |
| 3-28-05 | Sandra Saccoccia |
| Sandra Saccoccia | |
| Typed or Printed Name of person signing certificate | |


TRANSMITTAL LETTER

Enclosed are the following documents:

1. Transmittal Letter (1 page);
2. Information Disclosure Statement (4 pages);
3. Form PTO-1449 (2 pages);
4. Cited Art (19); and
5. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,


Charles E. Lyon, D.Phil.
Registration Number 56,630

CHOATE, HALL & STEWART LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000
(617) 248-4000

3904566

ATTORNEY'S DOCKET NUMBER: 2003882-0

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Applicant: Bipin Chandra Muljibhai Patel Examiner: Unassigned
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Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

☒ An *original* Information Disclosure Statement; or☐ A *supplemental* Information Disclosure Statement.Certificate of Mailing

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Date

3/28/05

Signature

Sandra Saccoccia

Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- [X] Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- [] Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - [] Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - [X] Before the mailing of a first Office action on the merits; or
 - [] Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ [X] A copy of each cited reference not indicated with an asterisk is included;
- ☐ [] Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

| Serial Number | Filing Date | Status |
|---------------|-------------|--------|
| | | |

- ☐ [] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ [] Does not contain non-English language citations;
- ☐ [] Includes one or more translations of a non-English citation; or
- ☒ [X] Does contain non-English language citations, of which the following is a concise explanation: WO 01/34196 is in German. Applicant has *not* prepared a translation of this PCT application into English. However, Applicant has enclosed a copy of related published US application 20030012325 which is a *continuation-in-part* of this PCT application. This *continuation-in-part* should allow the Examiner to determine whether the PCT application might be material to patentability and thus whether a translation of the PCT application would be worth obtaining.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC §102.

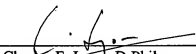
It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: March 28, 2005


Charles E. Lyon, D.Phil.
Registration Number 56,630

CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
(617) 248-5000
(617) 248-4000

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)



Applicant: Bipin Chandra Muljibhai Patel

Filing Date:
June 28, 2004

Group:

U.S. PATENT DOCUMENTS

| Examiner's Initials | U.S. Patent No. | Applicant | Issue Date | Class | Subclass |
|------------------------|-----------------|-----------|-----------------|-------|----------|
| | 5,443,813 | Hainfeld | August 22, 1995 | 424 | 1.17 |

U.S. PATENT APPLICATIONS

| Examiner's Initials: | Publication Number: | Applicant: | Publication Date: | Group: | Art Unit: |
|-------------------------|------------------------|----------------|-------------------|--------|-----------|
| | 20030012325 | Kernert et al. | January 16, 2003 | 376 | 202 |

FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Document No. | Country | Date | Translation | |
|------------------------|--------------|---------------|----------------|-------------|----|
| | | | | Yes | No |
| | WO 01/34196 | International | 17 May 2001 | | X |
| | WO 00/45826 | International | 10 August 2000 | | |
| | WO 00/44682 | International | 03 August 2000 | | |

OTHER DOCUMENTS

| Examiner's Initials | Citation (Including Author, Title, Date, Pertinent Pages, Etc.) |
|------------------------|--|
| | Cheng, et al., "Neutron-Activatable Glass Seeds for Brachytherapy", <i>Journal of Nuclear Medicine, Society of Nuclear Medicine</i> , 35(5): 242, 1994. |
| | Coderre, et al., "Control of Intracerebral Gliosarcomas in Rats by Boron Neutron Capture Therapy with p-Boronophenylalanine", <i>Radiation Research</i> , 129: 290-296, 1992. |
| | Fukumori, et al., Nano-Particulate Design and Preparation for Targeting and Controlled Release of Drugs", <i>International Conference on Processing Material for Properties</i> , 2000. |
| | Lawaczek, et al., "Gadolinium Neutron Capture Therapy (GdNCT) with MRI Contrast Media. In Vitro Studies", <i>Cancer Neutron Capture Therapy</i> , Pages 859-864, 1996. |
| | MacPherson, et al., "Dose Distributions and Dose Rate Constants for New Ytterbium-169 Brachytherapy Seeds", <i>Medical Physics</i> , 22(1): 89-96, 1995. |
| | Morris, et al., "Response of Rat Skin to Boron Neutron Capture Therapy with p-Boronophenylalanine or Borocaptate Sodium", <i>Radiotherapy and Oncology</i> , 32: 144-153, 1994. |
| | Morris, et al., "Response of the Central Nervous System to Boron Neutron Capture Irradiation: Evaluation Using Rat Spinal Cord Model", <i>Radiotherapy and Oncology</i> , 32: 249-255, 1994. |
| | Nairn, J.G., "Solutions, Emulsions, Suspensions, and Extracts", <i>Remington: The Science and Practice of Pharmacy</i> , Pages 721-752. |
| | Sezer, et al., Chemical Vapor Deposition of Boron Carbide", <i>Materials Science and Engineering B79</i> : 191-202, 2001. |

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Bipin Chandra Muljibhai Patel

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Group:

June 28, 2004

Thomas, et al., "Dodeca(Carboranyl)-Substituted Closures: Toward Unimolecular Nanoparticles as Delivery Vehicles for BNCT", *Chem. Commun.* 1884-1885, 2001.

Tokumitsu, et al., "Chitosan-Gadopentetic Acid Complex Nanoparticles for Gadolinium Neutron-Capture Therapy of Cancer: Preparation by Novel Emulsion-Droplet Coalescence Technique and Characterization", *Pharmaceutical Research*, 16(12): 1830-1835, 1999.

Turco, S., "Intravenous Admixtures", *Remington: The Science and Practice of Pharmacy*, Pages 807-820.

International Search Report issued for corresponding PCT application PCT/GB02/05927.

European Search Report issued for convention GB application 0131058.0.

EXAMINER /Melissa Perreira/

DATE CONSIDERED

05/14/2009

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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